DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2014

Yamaha Motor Company, Limited
c/o Mr. Alexander Schapovalov
TÜV SÜD America Inc.
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

Re: K140204
Trade/Device Name: JWX-2
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: June 26, 2014
Received: July 27, 2014

Dear Mr. Schapovalov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140204

Device Name
JWX-2

Indications for Use *(Describe)*
The device JWX-2 is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.08.28 10:05:43 -04'00'

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5. 510(k) SUMMARY

1. Submitter information

Manufacture Name: YAMAHA MOTOR CO.,LTD.
882 Soude,Naka-ku
Hamamatsu, Shizuoka 435-0054, Japan

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2. Date Prepared October 21, 2013

3. Device

Type in common name: Electric Power Assist Unit for Wheelchairs
Name: JWX-2
Classification Name: Wheelchair, Powered (21 CFR 890.3860)
Product Code: ITI
Device Structure: Right Power Wheel Unit
Left Power Wheel Unit
Battery
Battery Charger

4. Basis for the Submission: New device design

5. Predicate Device: SUNRISE MEDICAL, INC.
QUICKIE 2 POWER ASSIST WHEELCHAIR(K001491)

Urich Alber GmbH & Co. KG
e-motion Wheelchair Drive System (K003449)

6. Device Description

The device JWX-2 is an electric power assist unit for wheelchairs that turns a manual wheelchair into a power assisted wheelchair. The device supplies the assist power in response to the wheelchair handrim operating both push-and-brake forces in both directions. The user can operate the wheelchair just like a manual wheelchair with lighter hand force.

The device consists of the left/ right power wheel units, battery and the battery charger. The power wheel units replace the original wheels of the manual wheelchair. Each power wheel unit has its own hand rim that incorporates the torque sensor which detects the user's operation force.
Yamaha Ni-MH battery JWB2 and Yamaha Li-ion battery ESB1 can be used for the device. JWB2 is recharged with the charger JWC-2 and ESB1 is recharged with the charger ESC1. Both batteries can be charged in detached 'desktop' condition and the ESB1 can be charged also on the wheelchair condition. ESB1 does not supply the driving current during the charging to prevent the wheelchair to move.

The assist power of the device is adjustable.

The wheel locks of the manual wheelchair can be used to prevent the wheelchair from rolling and to keep the wheelchair complete stop like manual wheelchairs with the initial installation adjustment.

7. Indications for use

The device JWX-2 is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.

8. Comparison to Predicate Devices

The device has the similar technological characteristics as the predicate device. The microprocessors in both devices control the electrical current from the rechargeable batteries to the wheel-in motors in response to the user's handrim operations. Both devices use a mix of human and electrical power to propel the wheelchair and can be used with the device power turned off like a manual wheelchairs. See COMPARISON TABLE below.

9. Non-Clinical Testing

The device JWX-2 was tested with the following standards

ISO 7176-9: Third edition 2009-11-15, Wheelchairs - Part 9:
Climatic tests for electric wheelchairs.

ISO 7176-14: 2008, Wheelchairs – Part 14:
Power and control system for electrically powered wheelchairs and scooters – Requirements and methods.

ISO 7176-15 First edition 1996-11-15 Wheelchairs - Part 15:
Requirements for information disclosure, documentation and labeling

ISO 7176-21:2009, Wheelchairs – Part 21:
Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.

IEC 62304 First edition 2006-05, Medical device software:
Software life cycle processing

ISO 14971 Second edition 2007-03-01, Medical devices
Application of risk management to medical devices.

AAMI / ANSI / ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1:
Evaluation and testing within a risk management process. (Biocompatibility)

AAMI/ANSI/ISO 10993-5:2009, Biological evaluation of medical devices – Part 5:
Tests for In Vitro cytotoxicity.

IEC 60335-2-29:2002(Fourth edition)+A1:2004 , Household and similar electrical appliances - Safety - Part 2-29: Particular requirements for battery chargers

IEC60335-1:2001(Fourth edition)+A1:2004+A2:2006 , Household and similar electrical appliances - Safety - Part 1: General requirements

IEC 62133:2012 , Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

AAMI / ANSI / IEC 60601-1-2, medical electrical equipment - part 1-2:
general requirements for safety - collateral standard: electromagnetic compatibility - requirements and tests (edition 2:2001 with amendment 1:2004)
(aami/ansi/iec 60601-1-2:2001 with amendment 1:2004 is the u.s.. (General I (QS/RM))

10. Summary

The device JWX-2 has the same intended use and similar technological characteristics as the predicate device. The device does not raise any new questions of safety or effectiveness. The device is substantially equivalent to the predicate device.

COMPARISON TABLE

(Same performance are indicated by boldface.)

	QUICKIE 2 POWER ASSIST WHEELCHAIR	E-MOTION WHEELCHAIR DRIVE SYSTEM	JWX-2
510(k) Number	K001491	K003449	Subject Device
Intended Use	Quickie powered wheelchairs empower physically challenged persons by providing a means of enhanced mobility.	The e-motion Wheelchair Drive System is a Power Wheelchair Conversion Kit that adds a power assist to a manual wheelchair, thereby, turning a manual wheelchair into a power-assisted wheelchair. It is a push-and-brake assist working in both directions. The intended use is to provide mobility to persons limited to a seated position that are capable of operating a powered and manual wheelchair.	The device JWX-2 is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.
Total Weight	15.8kg(Ni-MH)	22kg(Li-ion)	17 kg (Ni-MH) 17.7kg (Li-ion)
Drive Unit Width (Hub Height)	95mm	93mm	91mm *There is no influence on stability. Rather, a user can go also to a narrower place.
Max. User Weight	120kg	**130kg**	**130kg**
Speed Range with Power Assist	**up to 6Km/h**	**up to 6km/h**	**up to 6Km/h**
Max Safe Slope	**6°**	**6°**	**6°**
Max Range per Charge	15km & above (Ni-MH)	25km & above	40km & above (Li-ion) 20km & above (Ni-MH) *More range per charge is benefitial for end users.
Type of Motor	DC Brush Motor	**DC Brushless Motor**	**AC servomotor (DC Brushless Motor)**
Rated Power of Motor	30mins rated 90W x 2	DC24V 60W×2	30mins rated 110W x 2
Battery	**Type: Ni-MH(Dry)** **Capacity: 24V 6.7Ah(Nom.)**	Type: Li-ion Capacity: 25.2V 6.45Ah x 2	**Type: Ni-MH(Dry)** **Capacity: 24V 6.7Ah(Nom.)** **Type: Li-ion(Dry)** **Capacity: 25V11.8Ah(Nom.)** ***Selectable**

COMPARISON TABLE(continued)

(Same performance are indicated by boldface.)

	QUICKIE 2 POWER ASSIST WHEELCHAIR	E-MOTION WHEELCHAIR DRIVE SYSTEM	JWX-2
Wheel Size	**24"/22"**	**24"/22"**	**24"/22"**
Tire	**Pneumatic**	**Pneumatic**	**Pneumatic**
Quick Release Axle	**QR only**	**QR only**	**QR only**
Left/Right wheel Synchronized Control	**Provided**	N/A Individual control	**Provided**
Regenerative Brake	**Provided**	**Provided**	**Provided**
Down Slope Speed Regulation	**Provided**	N/A	**Provided**
Driving Mode Selector (user operable)	N/A	M15: 2 power stages with remo-cont'r M14: preset only	Option (2 modes)
Handrim	**- Stainless steel** **- Dipped Vinyl Coated**	**– Stainless steel** **– Dipped Vinyl Coated** **– Removable rubber cover**	**- Stainless steel** **- Dipped Vinyl Coated**
Certification	**EN12184:2009 (Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods)** *** Power assist component (JW-II) supplied by YAMAHA MOTOR is certificated by TUV SUD.**	**EN12184:1999 (Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods)** **by TUV SUD**	**EN12184:2009 (Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods)** **by TUV SUD**